THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 16

UNITED STATES PATENT AND TRADEMARK OFFICE

_____

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

_____

Ex parte GEORGE P. SHIBLEY,
KAREN K. BROWN,
LESZEK J. CHOROMANSKI,
and SHARON A. BRYANT

_____

Appeal No. 1997-2512
Application No. 08/118,905[1]

_____

ON BRIEF

_____

Before KIMLIN, PAK, and DELMENDO, ***Administrative Patent Judges***.

DELMENDO, ***Administrative Patent Judge***.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's refusal to allow claims 12 through 15, which are all of the claims remaining in the application.

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[1] Application for patent filed September 9, 1993.

Claim 12 is representative of the subject matter on appeal and reads as follows:

12. A method of delivering an effective amount of biological or pharmaceutical material to an animal by providing a tube containing said biological or pharmaceutical material, which tube is sealed at its ends and is administered to an intended cite [sic, site] of the animal by penetrating the sealed tube at its lower section, followed by penetrating the tube at its upper section to release the material to the mucosal membrane of the animal.[2]

The prior art relied upon by the examiner are as follows:

Whittaker	2,066,868	Jan. 5, 1937
Frenkel et al. (Frenkel)	5,045,313	Sep. 3, 1991
Cassou et al. (Cassou)	5,190,880	Mar. 2, 1993

The prior art references of record newly relied upon by the Board are:

Kidder	4,792,333	December 20, 1988

Appellants' admission at page 1, lines 10-13 of the specification (hereinafter referred to as "the admitted prior art").

As a preliminary matter, we note that the examiner has expressly withdrawn the objection and rejections under 35 U.S.C. § 112. See the examiner's communication mailed May 14, 1996 and the last full paragraph on page 2 of the Answer. Therefore,

[2] Claim 12 was amended after appeal in an amendment filed concurrently with the Reply Brief on January 16, 1996. In a communication mailed May 14, 1996, the examiner indicated that the Reply Brief has been entered and that claim 12 has been amended. We note, however, that the appellants did not submit a corrected copy of the appealed claims with their Reply Brief, and that the amendment of claim 12 has not been clerically entered. For purposes of this appeal, we will presume that amended claim 12 has been clerically entered. Upon return of this application, the examiner should attend to the formal entry of the aforementioned amendment.

the issues relating to the § 112 rejections are not part of this appeal, and the only issues to be resolved in this appeal are as follows:

1. Whether the examiner erred by finally rejecting claims 12 and 13 under 35 U.S.C. § 102(b) as anticipated by Whittaker; and

2. Whether the examiner erred by finally rejecting claims 14 and 15[3] under 35 U.S.C. § 103 as unpatentable over Frenkel in view of Whittaker or Cassou.[4]

We ***reverse*** both the rejections.

In reaching our decision in this appeal, we have reviewed the specification, the claims, and the applied prior art, including all of the arguments advanced by the appellants and the examiner in support of their respective positions. As a result of this review, we make the determinations below.

Claim Interpretation

[3] The statement of rejection on page 3 (2nd full paragraph) of the Examiner's Answer indicates that claims ***12-***15 stand rejected under 35 U.S.C. § 103. However, it appears that this statement contains a typographical error, since only claims 14 and 15 are indicated as rejected under this same ground on page 5 (last paragraph) of the Answer and also on page 5 (paragraph 32) of the final Office action.

[4] The statement of rejection on page 3 (2nd full paragraph) of the Answer fails to mention Cassou as one of the references relied upon to establish obviousness. However, the Examiner's Answer at page 2 lists Cassou as one of the references relied upon to reject the claims on appeal. In addition, the statement of rejection on page 5 (paragraph 32) of the final Office action expressly includes Cassou as one of the references relied upon to support the examiner's conclusion of obviousness. Therefore, it appears that the examiner's omission of Cassou from the statement of rejection in the Answer was inadvertent. Accordingly, we will consider Cassou in this instance to avoid the possibility of piecemeal appeal and to ensure administrative efficiency.

We begin our consideration of the issues before us by determining the scope of the claimed subject matter. ***Gechter v. Davidson***, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997); ***In re Paulsen***, 30 F.3d 1475,1479, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994). Although claims are given their broadest reasonable interpretation during proceedings before the PTO, the interpretation must not be inconsistent with the one that those skilled in the art would reach. ***In re Cortright***, 165 F.3d 1353, 1358, 49 USPQ2d 1464, 1467 (Fed. Cir. 1999). Thus, we must interpret the claims by giving words their broadest reasonable meaning in their ordinary usage, taking into account the written description found in the specification. ***In re Morris***, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997).

The claimed subject matter is directed to "[a] method of delivering an effective amount of biological or pharmaceutical material to an animal." As recited in claim 12 above, the method is carried out "by providing a tube containing said biological or pharmaceutical material, which tube is sealed at its ends and is administered to an intended cite [sic, site] of the animal by ***penetrating the tube at its lower section, followed by penetrating the tube at its upper section to release the material to the mucosal membrane of the animal.***" (Emphasis added.) Thus, the subject matter of present claim 12 requires, *inter alia*, penetrating the tube at its lower section, followed by penetrating the tube at its upper section, to release the material to the mucosal membrane of the animal. According to the Ninth New Collegiate Dictionary, Merriam-Webster Inc.,

Springfield, MA (1986), a copy of which is attached to this decision, the term "penetrate" is defined as "to pass into or through," "to enter by overcoming resistance," or "to gain entrance to." The appellants' specification uses the term "penetrating" in a manner that is consistent with the ordinary meaning above. In the paragraph bridging pages 3 and 4 of the specification, the appellants state as follows:

> "To exit the pharmaceutical or biological material, the tube is ***adapted to open by penetrating it effectively to release or expel the material. The tube can be penetrated by means such as cutting***. Typically, the tube is first penetrated at a lower section and then at an upper section in order to effect a release of the biological or pharmaceutical material. As would be realized, upon cutting the tube, particularly a capillary tube, at the lower section, the biological or pharmaceutical material does not exit the tube. Consequently, spillage of the material and associate[d] negatives such as infection of humans can be avoided. Upon cutting the tube at the upper section, (below the plug) the biological or pharmaceutical material is released. Alternately, ***upon cutting*** the tube above or through the plug, ***a plunger can be used to expel*** the biological or pharmaceutical material from the tube by pushing the plunger down the tube." (Emphases added.)

Rejection under 35 U.S.C. § 102(b)

Claims 12 and 13 stand rejected under 35 U.S.C. § 102(b) as anticipated by Whittaker.

The examiner states:

> "Whittaker et al. disclose the use of a sealed tube, which contains a plug, to administer medicants orally. Both ends are sealed (see components 15 and 17 of the figures), and the plug is used to evacuate the liquid. The outlet (11) can be plugged as well (see column 2, first paragraph)."

See page 3 of the Answer. In responding to the appellants' arguments, the examiner also asserts as follows:

> "Appellants have argued that the difference resides in Whittaker's use of a bulb. Appellants have argued that the claimed invention relates to a facile method of delivery comprising cutting the device. The Examiner maintains that Whittaker discloses a method of delivering a pharmaceutical material to an animal via the use of a tube. ***A means of opening the tube or straw at one end to dispense the pharmaceutical material is an inherent property in a method of delivery, therefore the specific means of opening the tube is not patentable***." (Emphasis added.)

See page 5 of the Answer and page 3 of the final Office action.

We shall not sustain this rejection.

To anticipate a claim, each and every element set forth in the claim must be found, either expressly or inherently, in a single prior art reference. ***In re Schreiber***, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997); ***Verdegaal Bros. v. Union Oil Co.***, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir.) ***cert. denied***, 484 U.S. 827 (1987).

Here, a comparison of the subject matter of present claim 12 and Whittaker reveals that the examiner has failed to set out a ***prima facie*** case of anticipation. Starting at column 1, line 20, Whittaker discloses:

> "In accordance with the invention, a dispersible substance, such as a medicinal fluid or fluffy preparation, that is to be applied to delicate internal parts of the human body, such as the mouth cavity or nasal cavity of a person, is enclosed in a tubular container which permits direct discharge of its contents at the point of its application within the cavity of the body, the exterior parts of the container which come in contact with delicate interior parts of the body being kept in clean and sanitary condition and its contents being sealed and protected against contamination by a removable flexible coating enclosing the discharge portion of the container.
>
> As shown in Fig. 1 the dispensing unit comprises a cylindrical tube 10 of glass or similar material having at its front end a restricted discharge

> opening 11 and at its rear end an impelling opening 12, the tubular vessel containing a dispersible substance 13, such as a medicinal fluid or fluffy cream, which is to be applied to an accessible internal body portion of a person. The substance is held tightly sealed within the container by means of a cylindrical plug 14 at the impelling opening of the tube and a tubular coating 15 of a flexible substance, such as rubber, which seals the discharge opening 11 and extends lengthwise the tube to cover the part of the tube that is inserted into the cavity where it is to be applied. The plug 14 may be made of a plurality of layers of cotton felt saturated with a filler, such as a mixture of petrolatum and melted wax. The impelling opening and the adjacent rear end of the tube may be likewise enclosed by a flexible coating 17, of rubber, like the front portion of the tube. The two rubber coatings 15 and 17 are under tension and cling to the exterior of the tube 10, sealing up its interior and protecting the exterior of the tube against contamination. If required, by the consistency of the substance, the discharge opening 11 may be sealed with a readily removable plug 19 of sealing material, such as paper or rubber, before coating 15 is placed thereon."

See also Figure 1.

Although Whittaker's method is similar to the appellants' claimed method, we agree with the appellants that Whittaker discloses a dispensing technique that is completely different from that recited in present claim 12. Specifically, Whittaker discloses:

> "The fluid dispensing unit may be readily discharged and dispensed at any desired point in the mouth cavity or any other cavity of the body by ***removing the flexible coatings 15 and 17*** from the tube 10 and slipping a rubber neck 21 of a rubber bulb 22 over the rear end of the tube 10. The unit is then inserted into the cavity so that its discharge opening 11 faces the interior body portion to which it is applied, and ***by squeezing the bulb 22 the plug 14 is impelled by the compressed air from the bulb, the plug 14 acting as a piston and quickly discharging the fluid as desired***." (Emphases added.)

See column 2, lines 18-30. Thus, the squeezing of bulb 22 forces compressed air to act on plug 14, which in turn serves as a piston to expel the medicinal fluid onto the body

cavity.

The examiner has not pointed to any evidence showing that Whittaker discloses the steps of penetrating the lower section of the sealed tube, followed by penetrating the upper section of the tube, to release the biological or pharmaceutical material to a mucosal membrane of an animal. Nor has the examiner explained how these claim elements would be inherent in Whittaker's delivery method. Contrary to the examiner's allegation, the dispensing method as described in Whittaker would not meet the claim elements in question here. This is because claim 12 requires penetrating a lower section of the tube, followed by penetrating in the upper section to release the biological or pharmaceutical material to an animal. In Whittaker, the coatings 15 and 17 are first removed. But the removal of these coatings cannot reasonably be considered "penetrating" as required by the claims on appeal because there is nothing separate from the sealed tube entering into (or passing into or through) the sealed tube during the removal of these coatings. We also note that the seal (column 2, lines 3-8 and column 2, line 48 to column 3, line 1) covering discharge opening 11 is apparently broken by the force of the ejecting medicinal fluid or fluffy preparation. However, this breaking of the seal also cannot reasonably be considered to meet the limitation "penetrating" as recited in the claims on appeal because nothing separate from the sealed tube enters into the sealed tube during the breakage of the seal at discharge opening 11. Additionally, there is no penetration at the other end by squeezing bulb 22 to compress internal air, which in turn acts on the piston plug 14,

because the air does not penetrate from outside the sealed tube, which includes squeezing bulb 22.

With respect to the examiner's comment regarding inherency, a rejection based on a theory of inherency is not appropriate unless there is sufficient factual basis or sound technical reasoning to support such a theory. ***Continental Can Co. v. Monsanto Co.***, 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991); ***In re Oelrich***, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981); ***Ex parte Levy***, 17 USPQ 1461, 1464 (Bd. Pat. App. & Inter. 1990). Here, the examiner has not adduced any such factual basis or sound technical reasoning.

In the sentence bridging pages 7 and 8 of the Answer, the examiner alleges that the "[a]ppellants' use of a plunger to expel the substance from the device is the same function as the rubber bulb [sic], i.e. to expel the substance from the tube or device." However, the use of a plunger to expel the material, as described in the appellants' specification at page 4, lines 1-4, occurs after cutting (i.e., penetrating) the tube above or through a plug. In Whittaker, there is no penetration step. At best, Whittaker only discloses expulsion, which is auxiliary or alternative to the appellants' two-step penetration of the sealed tube to release the material. See page 3, lines 19-21, page 3, line 28 to page 4, line 4, and page 5, line 28 to page 6, line 3 of the appellants' specification.

Under these circumstances, we hold that Whittaker's delivery method does not meet the claim elements "by penetrating the sealed tube at its lower section, followed by

penetrating the tube at its upper section to release the material to the mucosal membrane of the animal," as recited in appealed claim 12. Accordingly, we are constrained to reverse the examiner's rejection of claims 12 and 13 under 35 U.S.C. § 102(b).

Rejection under 35 U.S.C. § 103

We next consider the rejection of claims 14 and 15 under 35 U.S.C. § 103 as unpatentable over the combined teachings of Frenkel and Whittaker, or over the combined teachings of Frenkel and Cassou.

According to the examiner, "[i]t would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ either [sic] the tube of Whittaker et al [or Cassou] to dispense the vaccine of Frenkel et al. because the art teaches that tube shaped devices are useful for buccal delivery of medicaments." See page 3 of the Answer. We disagree.

The initial burden of establishing a ***prima facie*** case to deny patentability to a claimed invention rests upon the examiner. ***In re Piasecki***, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984). In carrying out this burden, the examiner must consider each and every limitation. ***In re Geerdes***, 491 F.2d 1260, 1262-63, 180 USPQ 789, 791 (CCPA 1974).

Frenkel discloses the oral administration of *Toxoplasma gondii* (*T. gondii*) to cats. In particular, Frenkel states:

> "The present invention overcomes the problems described above and provides a method (and a corresponding vaccine) for the immunization of cats against *T. gondii* challenge which eliminates the phenomenon of oocyst shedding in the vaccinated cats.
>
> Broadly speaking, the method of the invention involves administering to cats (preferably orally) an effective amount of a vaccine comprising a specific mutant of *T. gondii* which has been found to immunize 84% of cats without the need of chemoprophylaxis."

See column 2, lines 38-47. The *T. gondii* vaccine is the subject of dependent claim 15 and falls within the scope of "biological or pharmaceutical material" as recited in appealed claim 12. See page 4, line 8 to page 10, line 21.

Frenkel describes the administration of the vaccine to cats as follows:

> "Clones of Ara-A resistant Toxoplasma were grown in human fibroblast tissue cultures for short periods of time, but were normally maintained as chronic infections in mice. These were injected either subcutaneously (sc) or intraperitoneally (ip) and to prevent illness and permit development of bradyzoites in tissue cysts, the mice were treated from days 3 to 14 with sulfamerazine-sodium (Sigma Chemical Co., St. Louis, MO) 15 mg/ 100 ml of water, given ad libitum to drink. After at least one month, a mouse infected with a particular strain was killed, bled to be checked for the development of antibody, and a brain smear examined by light microscopy for the presence of cysts of Toxoplasma. The carcass of a mouse infected with a given candidate strain was then fed to one or several seronegative, weaned kittens and the feces were examined for the presence of oocysts over the next 30 days."

See column 3, lines 40-56. At column 6, lines 24-26, Frenkel teaches: “In addition, while the bradyzoite cysts have been fed directly, if desired the vaccine may include a suitable carrier.”

However, in contrast to the subject matter of independent claim 12, from which claims 14 and 15 depend, Frenkel does not disclose or suggest the following:

1. “providing a tube containing said biological or pharmaceutical material";
2. “which tube is sealed at its ends and is administered to an intended cite [sic, site] of the animal”;
3. “by penetrating the sealed tube at its lower section";
4. “followed by penetrating the tube at its upper section";
5. “to release the material to the mucosal membrane of the animal.”

Recognizing the deficiencies of Frenkel, the examiner relies on Whittaker to show that one of ordinary skill in the art would have been motivated to modify Frenkel’s method by using the delivery device disclosed in Whittaker. As we discussed ***supra***, however, Whittaker fails to disclose claim elements 3 to 5 above. Nor is there any evidence to show that one of ordinary skill in the art would have found the appellants’ claimed administration technique to have been an obvious variation of Whittaker’s administration step (i.e., expulsion of the medicinal fluid by allowing compressed air generated from the squeezing of a bulb to act on a plug that performs the function of a piston). Therefore, even if Frenkel and Whittaker were to be combined as suggested by the examiner, the combination would

not result in the subject matter of independent claim 12. For these reasons, we hold that the subject matter of dependent claims 14 and 15 would not have been ***prima facie*** obvious within the meaning of 35 U.S.C. § 103 over the combined teachings of Frenkel and Whittaker.

We also agree with the appellants that Cassou likewise does not remedy the deficiencies of Frenkel. Cassou discloses:

> "The invention relates to a tube, known as a straw, for cryogenically preserving biological samples, in particular viral cultures, formed by a length of tubular envelope made of biologically neutral, substantially transparent polymer material, provided with a seal at each of its two ends and including, in the vicinity of a first end, a sliding stopper comprising an aqueous gel between two pads made of porous elastic material."

See column 1, lines 7-14. The appellants have acknowledged that Cassou "teaches how to make a tube of the type disclosed in the application." Page 3, Appeal Brief.

Further, at column 6, lines 63-68, Cassou teaches as follows:

> "It will be appreciated, of course, that, in order to recover the biological sample for use, the ends 11 and 12 are sectioned flush with the underformed zones that are beyond the seals, and that the sample is expelled by pushing the sliding stopper mechanically or pneumatically."

However, there is no disclosure or teaching in Cassou regarding the administration of a biological or pharmaceutical material as in the appellants' claimed invention or in Frenkel. Rather, Cassou is concerned with the cryogenic preservation of biological samples, notably viral cultures. See, e.g., column 4, lines 31-35 and the abstract. Cryogenic preservation is different from, and would not have suggested the administration

of a biological or pharmaceutical material to an animal. It then follows that one of ordinary skill in the art would not have found any motivation or suggestion to combine Frenkel and Cassou in the manner as suggested by the examiner.

Accordingly, we hold that the subject matter of claims 14 and 15 would not have been ***prima facie*** obvious within the meaning of 35 U.S.C. § 103 over the combined teachings of Frenkel and Cassou.

The examiner's rejections under 35 U.S.C. § 103 are reversed.

New Grounds of Rejection under 37 CFR § 1.196(b)

We enter the following new grounds of rejection under 37 CFR § 1.196(b):

Claims 12 and 13 are rejected under 35 U.S.C. § 102(b) as anticipated by the disclosure of Kidder.

Kidder discloses a method for administering drugs, as follows:

> "It is an object of the invention to eliminate the intermediate step of removing the drug dose contained within a unit package for administering the dose to the patient. The method of the invention comprises opening the package and using the opened package for delivering the drug dose directly into the mouth of the patient. After opening the package at both ends, one end is placed in a liquid and the other end is placed in the patient's mouth. The patient then draws the liquid through the package for delivering the dose and liquid into the mouth. This triggers the natural swallowing reflex and allows for easy swallowing of the liquid and the drug dose entrained within the liquid flow."

See column 3, lines 28-40, together with Figures 1 through 8.

Kidder's package is initially sealed, with the ends being sealed by providing bonded end joints, and is preferably constructed to have a tubular cross-sectional shape.

See column 3, lines 62-66 and column 4, lines 11 and 12. Then, to administer the drug dose, the ends of the package are opened by cutting along lines 60 and 61 as shown in Figures 2, 6, and 7. See column 7, lines 23-26. Although Kidder does not expressly state the order by which ends 60 and 61 may be cut, it is clear from reviewing the entire reference as a whole that either of ends 60 or 61 may be cut first. We base this factual finding on Kidder's disclosure of using various means, such as a constriction 15 (column 5, lines 41-44) or intermediate bends 70 and 71 formed in the shape of a gooseneck (column 6, lines 64-48), which would prevent the drug from falling through as a result of gravity when the package is held upright. Therefore, it would be immaterial as to which end is cut first.

Once cut, one end is placed within the patient's mouth, while the other end is positioned within a cup of liquid. See column 7, lines 38-40. The drug dose therein can then be released into the patient's mouth as the patient draws liquid through the package from the other end to the one end. See column 7, lines 26-28 and 51-54, together with Figure 8.

Moreover, the broadest definition of the term "animal," which is recited in present claim 12, is inclusive of human patients. In this regard, the term "animal" is defined in the dictionary as "any of a kingdom (Animalia) of living beings typically differing from plants in capacity for spontaneous movement and rapid motor response to stimulation." See page 86 of the Ninth New Collegiate Dictionary, a copy of which is attached herewith. Further, the term "mucosal membrane of the animal" appearing in the appellants' claim 12 covers

the human mouth; in fact, dependent claim 13 calls for the oral administration of the biological or pharmaceutical material.

Giving claims 12 and 13 the broadest reasonable interpretation in light of the specification and comparing the subject matter of these claims to Kidder, we find that each and every claim element is described in the Kidder for the reasons indicated ***supra***.

Accordingly, we determine that the subject matter of these claims is anticipated by Kidder within the meaning of 35 U.S.C. § 102(b).

Claim 14 is rejected under 35 U.S.C. § 103(a) as unpatentable over the combined teachings of Kidder and the admitted prior art.

Kidder does not disclose that vaccines can be administered according to the method described therein. However, the appellants have admitted that polio vaccine can be administered orally by embedding the vaccine in a sugar cube. See page 1, lines 10-13. Based on these prior art disclosures, it would have been ***prima facie*** obvious to one of ordinary skill in the art at the time of the appellants' invention to administer solid polio vaccine using Kidder's administration method, motivated by a reasonable expectation of attaining the benefits described in Kidder (e.g., consistent

and accurate dosages, easy and efficient administration without the need to remove the drug from the package or change it to a powdered form for mixing with food, complete identification of the drug, and tamper-evident packaging). See column 3, lines 41-64.

We have considered the experimental evidence in the present specification, but we do not find this evidence to be sufficient to rebut this §103 rejection. Specifically, Table 1 shows a comparison of the results of freezing, in terms of viable titer, of a *T. gondii* bradyzoite vaccine in straws according to the present invention with freezing the same vaccine in conventional liquid nitrogen vials. Tables 2 and 3 show the efficacy of the administration according to the present invention by comparing vaccinated cats with non-vaccinated cats using a direct agglutination test. However, the tests shown in the appellants' specification do not compare the subject matter of claim 14 with the closest prior art, which is Kidder. Moreover, the experiments summarized in Table 1 relate to viable titer after freezing of the liquid for storage purposes, and appellants state that DMSO stabilizer must be included as part of the vaccine preparation. See page 4, lines 5-28 and page 7, lines 26-28 of the appellants' specification. By contrast, claim 14 on appeal is neither limited to liquid vaccines that require freezing for storage nor vaccines that contain DMSO stabilizer. Therefore, we do not consider the claim on appeal to be commensurate in scope with the evidence of nonobviousness. ***In re Kulling***, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990).

Other Issue(s)

The English language abstract of French patent publication FR 2,686,247[5] discloses:

> "The container consists of a narrow tube (1), open at both ends (11,12), which may be sealed at one or both ends by a film of plastics material (4,4'). The film is secured to the external side walls of the tube by adhesive or thermal treatment.
>
> The film is of a material and thickness such that it is easy to pierce, and extends for a small longitudinal distance along the tube walls. The tube contains a biological or medical substance and/or a gas, typically an inert gas."

The substance may be animal semen for artificial insemination.

It appears from the English language abstract that this French reference may anticipate or render obvious the subject matter of the claims on appeal. Upon return of this application, the examiner should obtain a full English translation of FR 2,686,247 to consider the reference in its entirety to determine whether the French patent publication as a whole anticipates or would have rendered obvious the claimed subject matter on appeal.

Summary

The examiner's rejection of claims 12 and 13 under 35 U.S.C. § 102(b) as anticipated by Whittaker is reversed.

The examiner's rejections of claims 14 and 15 under 35 U.S.C. § 103 as unpatentable over Frenkel in view of Whittaker or Frenkel in view of Cassou are reversed.

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[5] Although the Supplemental Information Disclosure Statement filed February 13, 1995 appears to comply with the requirements of 37 C.F.R. §§ 1.97 and 1.98, the examiner crossed out FR 2,686,247 from the PTO-1449 form and did not consider it. Therefore, FR 2,686,247 is not officially of record.

However, pursuant to 37 C.F.R. § 1.196(b), claims 12 and 13 are newly rejected under 35 U.S.C. § 102(b) as anticipated by Kidder.

Also, claim 14 is newly rejected under 35 U.S.C. § 103(a) as unpatentable over Kidder and the admitted prior art.

Time for taking action

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 1.196(b). 37 C.F.R. § 1.196 (b) provides that, "A new ground of rejection shall not be considered final for the purposes of judicial review."

37 C.F.R. § 1.196(b) also provides that the appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (37 C.F.R. § 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
>
> (2) Request that the application be reheard under 37 C.F.R § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

REVERSED
37 C.F.R. § 1.196(b)

EDWARD C. KIMLIN Administrative Patent Judge	)	
CHUNG K. PAK Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
ROMULO H. DELMENDO Administrative Patent Judge	)	

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